King, Valerie A.

From: Gogova, Maria
Sent: Thursday, August 07, 2003 2:43 PM
To: King, Valerie A.
Cc: Mawyer, Denise T.
Subject: FW: MARL Study Supplies

DSS:

Revised MARL Study Supply Need..

Valerie,

I do not know, whether my assumption while calculating the additional cigs. is correct or not, but see what I came up with (highlighted in red) at attached documents.
Let me explain why I used only 64 subjects instead of 80.
What we want to do is to recruit overall 240 subjects for Check in Day -3 to be sure than we have enough subjects for randomization. We calculating only with 192 subjects to complete the short term study, which means 64 subjects per each group.
Also see below par of the amendment Mike just sent to us:

"The first two paragraphs and table in Section 3.1 - Design will be amended to:

This research study will utilize a randomized, open-label, controlled, forced-switching, parallel design conducted at two research centers. Up to 240 self-affirmed Marlboro adult smokers with a daily cigarette consumption between 10 and 30 cigarettes/day will be initially enrolled into the Acclimation/Baseline period (Days -2 and -1) to better ensure that at least 192 healthy, smoking adult male and female subjects are available for randomization into one of three parallel groups with 64 subjects in the Marlboro group, 64 subjects in the Marlboro LIGHTS group, and 64 subjects in the Marlboro ULTRA LIGHTS group.

Beginning on the morning of Day 1 and continuing through the end of Day 8, the subjects will participate in one of the following groups:

Group (Days 1 - 8)	Smoking Product	No. of Subjects
A	Marlboro	64
B	Marlboro LIGHTS	64
C	Marlboro ULTRA LIGHTS	64"

Please let me know what you think

Maria

-----Original Message-----
From: King, Valerie A.
Sent: Thursday, August 07, 2003 1:28 PM
To: Gogova, Maria
Cc: Mawyer, Denise T.
Subject: MARL Study Supplies

Maria:
Please see attached my calculation for total supply needed with revised numbers. I did not include any additional "buffer" amounts for the long term study.

PM3006735602

Source: https://www.industrydocuments.ucsf.edu/docs/njpx0001

If you think these numbers are okay, I will work with Denise to coordinate production/constituent testing.

Thanks,
Valerie

PM3006735603

Source: https://www.industrydocuments.ucsf.edu/docs/njpx0001